

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

Application No.

09/980,062

Examiner

Jeffrey E. Russel

Applicant(s)

NAIDU, A SATYANARAYAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 29 August 2005 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☒ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☒ C. Other See attachment.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings:
 - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☐ C. Other _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: See attachment.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

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1. The proposed amendment to the paragraph at page 10, line 35 to page 11, line 3, of the specification is in improper format under 37 CFR 1.121(b)(1)(ii) because it deletes a word, “heparin”, which was not present in the previous version of the paragraph. Note that the previous version of the paragraph contains the word “heparan”.

The proposed amendments to claims 3, 14, 20, and 40 are in improper format under 37 CFR 1.121(c)(2) because they delete a word, “heparin”, which was not present in the immediate prior version of the claims. Note that the immediate prior version of the claims contains the word “heparan”. The proposed amendment to claim 14 is also in improper format under 37 CFR 1.121(c)(2) because it re-inserts the word “gelatin” at line 9 without underlining. The proposed amendment to claim 19 is in improper format under 37 CFR 1.121(c)(2) because it includes underlining for the phrase “, not including gelatin,” even though the phrase was present in the immediate prior version of the claim. The proposed amendment to claim 20 is also in improper format under 37 CFR 1.121(c)(2) because it omits the comma which occurred after “including”, and inserts a comma after “gelatin”, without strikethrough and underlining as required by 37 CFR 1.121(c)(2).

2. The proposed amendments, had they been entered, would have overcome the objections and rejections set forth in sections 2 and 3 of the final Office action, and would have overcome the objections to claims 20 and 36 set forth in section 4 of the final Office action. There was no response to the objection to claim 104 set forth in section 4 of the final Office action.

3. At page 36 of the response, Applicant states that “the examiner asserts that the declaration should be ignored”. This is not an accurate summary of the examiner’s position. The examiner also does not state or imply that a declaration under 37 CFR 1.132 must be based

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upon direct testing. It is clear, given the examiner's discussion from page 9, last three lines, through page 12, of the final rejection that the declaration has not been ignored by the examiner. The examiner does hold that the declaration is insufficient to rebut the prior art rejections set forth in the final Office action.

Applicant states that he is not required to provide an explanation in the specification concerning how his invention works. The examiner agrees. However, if Applicant chooses not provide an explanation as to how his invention works, then Declarant can not make unsupported statements as to how the invention works. Dr. Barron's explanation that the positive N-terminus region must bind to a negatively charged substrate is unsupported because Applicant never provided any explanation as to how the invention works, and because the explanation contradicts circumstances (e.g., immobilization on uncharged triglycerides) which the specification originally disclosed would work. When the application is considered in its entirety, and when originally-filed claim 3 is considered in its specifics (see the last word in the claim), it is clear that it was originally disclosed that lactoferrin can be immobilized by its N-terminus to triglycerides, which are uncharged molecules. The only evidence of record of any inconsistency between Applicant's overall teachings and Applicant's initial recitation of triglycerides and other lipids is the Barron declaration, and an unsupported opinion declaration does not preponderate over Applicant's original disclosure.

Applicant points to specific proteins and polysaccharides disclosed in the specification, states that they all contain negatively charged regions, and concludes that the Barron declaration is not inconsistent with the claimed invention. However, all of the specific proteins and polysaccharides mentioned by Applicant also contain positively charged and neutral regions in

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addition to negatively charged regions (e.g., the proteins all comprise a positively charged N-terminus and positively charged lysine, arginine, and histidine sidechains). Again, there are specifically disclosed substrates, i.e. triglycerides, which do not comprise negatively charged regions. The Baron declaration's assertion that immobilization occurs through charge attraction is inconsistent with the invention as originally disclosed and as currently claimed.

At page 39 of the response, Applicant contends that the word "should" as used by Declarant to express condition, i.e. as a synonym for "must". Applicant cites Merriam-Webster's Collegiate dictionary in support. However, the Dictionary makes clear that "should" can also be used to express expediency (see definition 2) or probability (see definition 4). Applicant has not explained how it is known in which sense "should" was used by Declarant. The best evidence of which definition of "should" was intended by Declarant would be a statement by Declarant. In the absence of such a statement, the examiner will chose a definition which does not result in a contradiction between the declaration and the disclosure of the invention. Because interpreting "should" to mean "must" would result in a contradiction with the original disclosure of the invention as outlined above, the examiner interprets "should" as meaning expediency or probability.

The examiner maintains the prior art rejections for the reasons of record (with the exception of certain claims as discussed below).

At pages 38 and 42 of the remarks, Applicant's attorney asserts that the original disclosure of nucleic acids, nucleotides, lipids, adenosine triphosphate, and triglycerides as useful substrates upon which lactoferrin could be immobilized was incorrect and that these compounds are actually inoperable substrates. These arguments are unconvincing because these

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compounds were originally disclosed and claimed as useful substrates. If there is any contradiction between the original disclosure and Applicant's arguments or a declaration filed under 37 CFR 1.132, the contradiction is always resolved in favor of the original disclosure. Subsequent deletion of specific compounds from the disclosure does not eliminate the original admission that these compounds are useful substrates upon which lactoferrin can be immobilized. Even assuming that it is true that compounds which are not negatively charged or compounds which are too small can not serve as useful substrates, at best this would raise issues under 35 U.S.C. 112 with respect to Applicants' claims. Claims which include a substantial measure of inoperative embodiments are fairly rejected under 35 U.S.C. 112. In re Corkill, 226 USPQ 1005, 1009 (CAFC 1985). Note that there is still no guidance in the specification that there is a charge limitation or size limitation upon the substrates which can be used. Note there is nothing which requires, e.g., the substrates of claim 1 or the proteins, polysaccharides, or nucleic acids of claim 2, to be negatively charged or to have a size larger than that of lactoferrin.

4. Upon review of the rejections, claims 2, 18, and 103 are no longer rejected over the WO Patent Application 91,13982 because these claims were amended to delete lipids from the list of possible substrates.

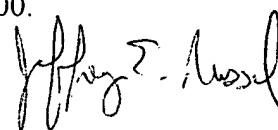
5. For purposes of appeal, the proposed amendment will not be entered, and the status of the claims will be: Claims 6-10, 14-17, 40-49, 51, 59-61, 63, 66, 67, 69-85, 91, 93-100, and 118 are allowed; Claims 3, 4, 12, 13, 21, 23-27, 29, 30, 33-37, 56-58, 62, 64, 65, 68, 87-90, 92, 105, 107-114, 125, 130, 139-141, 152, 155, 156, 160, 161, 166-170, 174, 177, 178, 182, 183, 188-192, 198, and 199 are objected to; and Claims 1, 2, 5, 11, 18-20, 22, 28, 31, 32, 38, 39, 86, 101-104,

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106, 115-117, 119-124, 126-129, 131-138, 142-151, 153, 154, 157-159, 162-165, 171-173, 175, 176, 179-181, 184-187, 193-197, and 200-202 are rejected.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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September 7, 2005